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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/621,620 | 07/17/2003 | Graham M. Clarke | 57901US005 | 1875 |
| 32692 | 7590 | 10/12/2006 | EXAMINER | |
| 3M INNOVATIVE PROPERTIES COMPANY PO BOX 33427 ST. PAUL, MN 55133-3427 | | | WITCZAK, CATHERINE | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3767 | |
| DATE MAILED: 10/12/2006 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/621,620

Applicant(s)

CLARKE ET AL.

Examiner

Catherine N. Witczak

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 19-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 8/4/2006.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

~~~~~ 10/2/06

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:


A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1-8 and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Sherman et al (US 2002/0020688).

Sherman et al disclose in Figure 3B a microneedle device comprising a first major surface (300), a plurality of microneedles (100) formed of polymers (paragraphs 0061) comprising a base that is tapered to a flat truncated tip distal the base (Figure 3A). Sherman et al further disclose in paragraphs 0038 and 0039 the microneedle capable of comprising a solid cross-sectional area of 20 square micrometers or more at a distance of 0.98h from the base; the base area capable of being 900 square micrometers or more, and the height base ratio being capable of being 3:1 or more. Sherman et al also disclose in these paragraphs a microneedle device capable of having a cross-sectional area of no more than 25% of the base on a plane located at a distance of 0.98h from the base.

Sherman et al disclose in paragraph 009 the method of using the microneedle device (531) comprising the step of contacting the skin (542), and forcing the microneedle device against the skin.




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2. Claims 9-16 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Gonnelli (US 2003/0135167).

Gonnelli discloses in Figure 11 and paragraphs a microneedle device comprising a first major surface (140), a plurality of microneedles (182, 184) formed of polymers (paragraphs 0015 and 0016) comprising a base that is tapered to a flat truncated tip distal the base. Gonnelli further discloses in paragraphs 0075 and 0076 the flat tip capable of comprising an area of between 20 and 100 square micrometers and the base are capable of being 900 square micrometers or more, and the height base ration being capable of being 3:1 or more. Gonnelli also disclose in these paragraphs a microneedle device capable of having a cross-sectional area of no more than 25% of the base on a plane located at a distance of 0.98h from the base.

Gonnelli discloses in paragraph 0009 the method of using the microneedle device comprising the step of contacting the skin and forcing the microneedle device against the skin.

### ***Response to Arguments***

3. Applicant's arguments filed 8/4/2006 have been fully considered but they are not persuasive. Applicant argues that Figure 11 of Sherman does not possess a flat tip, but rather a sharp circular edge at the tip of the needle. However, even if one were to assume that this is the case, it is still inherent that even a "sharp circular edge" must have some width to it, and thus inherently possesses a flat tip.
4. Applicant's arguments with respect to claims 9-16 and 18 have been considered but are moot in view of the new ground(s) of rejection.
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*Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine N. Witczak whose telephone number is (571) 272-7179. The examiner can normally be reached on Monday through Friday, 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

cw

*Witczak* 10/2/06

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

*Kevin C. Sirmons*

*W*